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Administrator Lisa Jackson
USEPA Headquarters
Ariel Rios Building
1200 Pennsylvania Avenue NW
Mail Code: 1101A
Washington DC 20460

Re: NRDC letter of October 3, 2011

Dear Administrator Jackson:

The purpose of this letter is to respond to the letter to you from Jennifer Sass at the Natural Resources Defense Council (NRDC) dated October 3, 2011 regarding the EPA's pending Integrated Risk Information System (IRIS) assessment of hexavalent chromium. I served on the expert peer review panel that recently reviewed the EPA's draft document, and I was explicitly mentioned and criticized in the NRDC's letter. While there are numerous technical inaccuracies and misstatements in their letter, I am particularly concerned about and feel I must specifically respond to the statements about me and my role in this assessment, since they attack me as an individual and professional and also call into question the EPA's process and the integrity of its review panel and its findings.

First, by way of background, I am an academic scientist and a molecular toxicologist who focuses principally on toxic metals including arsenic and chromium. I received my Ph.D. from Cornell University and did my postdoctoral training at Dartmouth College with the late Karen Wetterhahn, who was considered at the time of her tragic death in 1997 to be one of the world's top experts on chromium chemistry, biology and toxicology. It was in her laboratory that I first began my own research program on chromium in 1985, and I have been doing basic research on chromium for the past 26 years. I started my own independent laboratory at Dartmouth in 1988 and remained there, rising to tenured full professor at Dartmouth Medical School, until 2008 when I became the Chief Academic and Scientific Officer and a Senior Scientist at the Marine Biological Laboratory in Woods Hole MA where I also have an appointment as a Professor of Pathology and Laboratory Medicine at Brown University.

I am considered one of the leading independent experts on chromium toxicology, which is why I was invited to participate on the expert panel. I previously served on the EPA's Science Advisory Board Framework for Metals Risk Assessment panel (2004) to develop new risk assessment strategies for toxic metals and have served on many other independent expert panels in a similar capacity. I have been continuously funded by the National Institutes of Health (NIH) – principally through the National Institute for Environmental Health Sciences (NIEHS) and the National Cancer Institute (NCI) – as well as by the National Science Foundation (NSF) and by

other federal and non-federal non-profit agencies, for my entire career. My studies are reviewed and selected for funding via the peer-review process, and the results of these studies are published via the peer review process.

I should also note that, while at Dartmouth, I was the Principal Investigator and Director of the Dartmouth Superfund Research Program (SRP), which was initiated by me and Karen Wetterhahan in 1995 and which I directed from 1997 to 2008. When I moved to the MBL, I stepped down as Director but I remain as a research project leader in that program and am also affiliated with the Brown SRP program. As you know, the SRP program was started by and previously jointly funded by EPA and NIEHS, and is now funded and administered by NIEHS but with close ties to the EPA, the Center for Disease Control and Prevention (CDC) and their Agency for Toxic Substances and Disease Registry (ATSDR), and closely aligned with their missions to understand and ameliorate the adverse effects of toxic substances in the environment on human health. I have worked closely for many years with Region I EPA and ATSDR through our SRP program as well as several New England state agencies. The Dartmouth SRP program is focused exclusively on toxic metals, and through that program, my colleagues and I developed an international reputation for performing cutting edge research and assessment of toxic metals and human health.

My lab was the first to discover and report that arsenic is a potent endocrine disruptor [1-8] (as is chromium, see [1-3]), and more recently we demonstrated that arsenic also suppresses innate immune response [9,10], resulting, for example, in a substantial compromise in the ability of mice to recover from influenza infection [11]. My lab, among others in the Dartmouth SRP program, was also instrumental in assisting the EPA in the 1999 and 2001 National Research Council (NRC) reviews that led to a lowering of the drinking water standard from 50 to 10 parts per billion, and my lab's work was specifically cited by then EPA Administrator Christie Todd Whitman in Congressional Testimony as key new evidence that led EPA to promulgate the new drinking water standard. Current NIEHS Director Linda Birnbaum has often cited our arsenic research in her public comments and testimony before Congressional committees and other stakeholders. While at Dartmouth I also founded and was the director of the Center for Environmental Health Sciences, which remains as a strong interdisciplinary program at Dartmouth that more broadly examines the environment and human health and which currently manages the Dartmouth SRP and three other large, interdisciplinary program projects.

As this background illustrates, I am, and have always been an independent, principally federally-funded basic researcher doing fundamental research on the mechanistic basis for the toxic effects of chromium and arsenic. For the record, I am not, nor have I ever been, funded by industry for any of my chromium (or arsenic) research (as incorrectly stated in the NRDC letter, page 2, second paragraph). Thus, the implication that I "work for industry" is false and appears to be meant to label me in order to discount my expert opinions regarding hexavalent chromium and those of other members of this panel with which the NRDC and other special interest groups apparently disagree. Further in that same paragraph (page 2, paragraph 2) of the NRDC letter it states that I am "a litigation witness for PG&E ..." which is also false. Many years ago I did consult with PG&E on a chromium-related litigation matter that was settled. More recently I worked with them on another non-litigation matter involving former manufactured gas plant residues in the San Francisco area, serving as a toxicology expert for them, and serving as a

toxicology liaison with the State agency workers from CA EPA, officials from the City, and local residents and other stakeholders. Based on that consulting relationship, this summer I was asked by PG&E if I could serve in a similar capacity to provide toxicology advice to them, to the Hinckley CA community, and to the Lahontan CA water board as they discussed hexavalent chromium remediation strategies for the legacy contamination in Hinckley and the potential exposure and human health implications of those strategies. But while the water board has legal authority this is not, to my knowledge, a litigation matter per se – so far as I know there is no lawsuit pending with PG&E, nor am I involved in any litigation associated with Hinckley CA -- and my June 2011 declaration that the NRDC letter cites is simply a formal written response I was asked to write to the Lahontan water board as a follow-up to verbal comments I gave them and a draft decision they provided to PG&E regarding their clean-up strategy and the current controversy over the interpretation of a public health goal versus a regulatory and clean-up standard.

With regard to any potential conflict of interest, I had indicated to ERG Inc. my previous consulting with PG&E as well as other previous and current consulting, as part of my conflict of interest review in 2010 in preparation for the EPA's chromium expert panel review, and it was determined that there was no conflict. When PG&E initially contacted me about my potential role at the Hinckley site this summer – almost a year after I had been engaged by ERG for the EPA panel and after the majority of our work had been completed -- I immediately contacted ERG before making any decision, and ERG concluded that this did not represent a significant conflict of interest, particularly since the consulting would involve informal “town meeting” style formats and since it would follow after my principal involvement in the EPA review. At that point I had completed and submitted my preliminary review, participated in the public meeting and committee review in Washington DC, and amended my written comments for final submission as a follow-up to our public discussion.

I should also note that in addition to naming me in their letter, the NRDC also named Dr. Stephen Patierno who was also on the expert panel. The letter implied that Dr. Patierno and I were not only working together but were somehow overseeing and coordinating the efforts of ToxStrategies Inc. regarding the new chromium studies being concluded this year. Again, for the record, I do not now, nor have I ever worked for ToxStrategies, I am not involved in any way in those emerging studies, and I did not in any way know of, or coordinate any of the public comments that day. Moreover, I had not actually seen Dr. Patierno, nor communicated with him, for perhaps two years or more prior to seeing him at the May 2011 public hearing session of the expert review panel. The chromium field is small, and so in that sense he is a colleague (and I should note a competitor for NIH grants) that I have known for over twenty years, but we usually just see each other once a year or so at the annual Society of Toxicology meeting. The implication that we are somehow in collaboration behind the scenes is also absurd and patently false, and I am appalled at how irresponsible the NRDC was in making false allegations against me – and I assume also against Dr. Patierno – without the most basic fact-checking or confirmation.

Finally, I would like to make a more general comment regarding another statement in the NRDC letter because I think this substantially impacts not only this chromium review, but other external scientist-participatory processes within the EPA as well. In the fourth paragraph of page

2, the NRDC cites an article by Dr. David Michaels, which they state is a warning against appointing “product defense scientists” to advisory panels. As a toxicologist, I am deeply troubled by this statement and its implications. First, most of the toxicologists I know have done some consulting at one time or another. I believe this is not only acceptable but is an important activity. While most of us work in the laboratory or clinic, consulting provides an opportunity to apply our knowledge and experience to real-world situations, where “the rubber meets the road.” Were we not to do so, many stakeholders would find themselves having to make decisions in the absence of, or with incomplete knowledge of the latest science and our overall understanding of the adverse effects of chemicals on the environment and on human health. Thus, working toxicologists are often sought – and this is appropriate in my view – to provide insight into specific toxicology issues by various stakeholders. Second, in my experience most of these situations are non-litigation cases; but even in those cases, good toxicology is important to provide or the legal system is faced with very difficult decisions in the absence of this knowledge. But most importantly, it is important to recognize that there are at least two sides to every debate. And as a scientist, I am supposed to be as objective as possible in each situation. For any given circumstance where we are looking at a potential chemical exposure and asking whether there may be an adverse effect, we must acknowledge that the answer might be “yes,” but the answer might also be “no.” I assess each potential consulting matter as well as my own research results through this objective lens.

As I think is typical for academic scientists like me, my consulting is a very small part of my overall professional effort and is rather ad hoc. I do not advertise for or seek consulting opportunities, and those cases that I have worked on are always a result of someone seeking my expertise. Over the years I have worked on a few dozen individual cases and these range from individuals who are concerned about a household issue to small businesses to large corporations to schools and municipalities. And I have turned down perhaps four times as many potential clients than I have taken on because I did a preliminary assessment and told them I could not help them. Most of my cases have been non-litigation matters where someone is simply seeking knowledge to make an informed decision. But in litigation terms, I would say I have worked about equally for stakeholders who, if it had involved litigation, would traditionally be considered either defendants or plaintiffs. So the notion that I am “pro-industry” or principally work on their behalf is not true, as any simple examination of my consulting record would reveal.

More importantly, I believe it would do great harm to the EPA and others to exclude any toxicologist who has worked for a for-profit client, the so-called “product defense scientist” cited by the NRDC. First, it would exclude many, perhaps most good toxicologists in a given area. Second, as indicated, many toxicologists like me have worked on “both sides of the isle” – so would someone be excluded who had ever worked for an industry client under any circumstance? I think this would be a big mistake both because it excludes good people and because it assumes bias (but only in one direction) by the scientist if they have ever consulted with the private sector. Third, this assumes that industry is always “wrong” on a given issue and anti-industry stakeholders are always “right.” Painting with such a broad brush is, in fact, a strong form of bias and is the antithesis of good science that looks objectively – and skeptically – at any claims unless and until the science supports such a conclusion. And finally, as they say: “what is good for the goose is good for the gander.” If “pro-industry” experts are excluded, so

too should be “anti-industry” experts who have worked with or are working with plaintiffs, advocacy groups or others with their own “anti-chemical” or “anti-industry” agenda. Because one could argue that this is also a significant conflict of interest for such an expert, since a scientist on a panel who influences the outcome to overstate the toxicity of a chemical could arguably be seen as doing so to enhance his or her own abilities to garner positive results for plaintiffs and other stakeholders by supporting their claims of some harm from that chemical.

In conclusion, the charges aimed against me in the NRDC letter are false and baseless. I believe that the ERG put together an excellent panel of experts to review hexavalent chromium on behalf of the EPA, and that we did a very thorough and thoughtful job in updating this assessment with a comprehensive view of what chromium does and does not do. There is growing consensus, as indicated by the individual reviewer comments and by the discussion at the review session, that the emerging studies should be looked at very carefully before a final document is produced, and that there were other significant aspects of the draft document that required significant revision. In particular, there is growing consensus that a mutagenic Mode of Action (MOA) for chromium is unlikely when one views the entire chromium literature objectively through a modern lens. The EPA administrator who opened the meeting said it best when he stated that he did not want the EPA to just do it quickly, he wanted them to get it right. I concur wholeheartedly. He encouraged the panel to be as critical and comprehensive as possible, and I believe we fulfilled that charge and produced an excellent set of reviews of the draft document that we urged EPA to consider just as thoughtfully before producing a final document. I also believe that the panel represented a very good cross-section of the best expertise in the field and that the review was fair and comprehensive. I would urge the EPA to not bow to external pressures to do it quickly, or to dismiss some or all of the panel’s comments based on the NRDC’s charges and clear bias. I look forward to the EPA’s final evaluation of chromium toxicology and hope that you take full advantage of the expertise of the panel and the comments they provided to the agency on this important topic. I am happy to continue to be of service to the EPA in any capacity as it moves forward with this process.

Sincerely,

A handwritten signature in dark ink, appearing to be 'JW Hamilton', written in a cursive, flowing style.

Joshua W. Hamilton Ph.D.

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